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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/827,307

04/20/2004

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31894-202097

2558

26694

7590

05/28/2008

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EXAMINER

FISHER, ABIGAIL L

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/827,307	Applicant(s) ZEMEL ET AL.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-17, 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/14/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Amendments/Remarks filed on February 14 2008 is acknowledged. Claims 8-9 and 18 were/stand cancelled. Claims 1-7, 10-17 and 19-22 are pending.

Terminal Disclaimer

The terminal disclaimer filed on April 3 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6384087 and any patent granted on Application Number Application No. 10/066057 and 10/827296 have been reviewed and are accepted. The terminal disclaimer has been recorded.

Previous Rejections

The rejection of claims 1-7, 10-17, and 19-22 under 35 U.S.C. 102(a) as being anticipated by Zemel et al. (FASEB J. June 2000, 14(9) 1132-8.) is **withdrawn** in light of Applicant's declaration under 37 C.F.R. 1.132 filed on February 14 2008.

The declaration under 37 CFR 1.132 filed February 14 2008 is sufficient to overcome the rejection of claims 1-7, 10-17 and 19-22 based upon Zemel et al.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either

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reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 10-17 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 4-7, 10, 12-13 and 19 are vague and indefinite. All of the claims contain the phrase "at least about". "At least about" is vague and indefinite because it is unclear what constitutes the lower limit for the particular amount being claimed.

For instance, claim 1 indicates "at least about 773 mg per day"; however it is unclear if the lower limit of the dosage is at least 773 mg per day or about 773 mg per day.

For the purposes of applying art, "at least about" will be interpreted as stating "at least".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10-17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Study: Calcium May Curb Weight Gain in Young Women (<http://www.sciencedaily.com/releases/19991041990421073608.htm>, April 21 1999, referred to in the Office action as “Science Daily”) in view of Summerbell et al. (BMJ, cited in the Office action mailed on December 28 2007).

Applicant Claims

Applicant claims a method of inducing weight loss and/or increasing the metabolic consumption of adipose tissue in an individual suffering from obesity, wherein obesity is selected from the group consisting of Grade I, Grade II and Grade III obesity, wherein Grade I obesity being moderately overweight with BMI values of about 25.0 to 29.9, Grade II obesity being severely overweight with BMI values of about 30 to 39.9, and Grade III obesity being massive or morbid obesity with BMI values of about 40.0 or greater, wherein the method comprises in combination during a period of time: (a) administering to the obese individual one or more servings of one or more calcium-containing product(s), wherein the one or more servings comprises an amount of dietary calcium of at least about 773 mg per day, sufficient to induce weight loss, and/or increase the metabolic consumption of adipose tissue; and (b) restricting said obese individual to a caloric intake below ad lib in a range of about 200 kcal to about 2500 kcal per day, wherein consuming the calcium-containing product(s) during the period of time produces a benefit attributable to the calcium selected from the group consisting of inducing weight loss and/or increasing the metabolic consumption of adipose tissue in the obese individual, and wherein the individual is a woman and the one or more servings comprises at least about 57 servings of dairy per month.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Science Daily is directed to a study of the effect of calcium on weight gain. It is disclosed that when overall calorie consumption is account for, calcium not only helps to keep weight in check but can be associated specifically with decreases in body fat

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(paragraph 1). It is disclosed that when women of the study consumed a diet of 1900 calories or less, those who consumed an average of 1000 mg of calcium per day showed an overall decrease in body weight (paragraph 4 and 5) especially when compared to women those consumed less than 1900 calories but averaged less than 780 mg of calcium per day. The women who averaged less than 780 mg of calcium actually gained body fat mass over the same period (paragraph 4). Women who received their calcium from dairy sources such as milk, yogurt and cheese showed more benefits than those who primarily used non-dairy sources such as vegetables, nuts, beans, and calcium supplements (paragraph 8).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Science Daily does not specify utilizing calcium to induce weight loss in obese women. However, this deficiency is cured by Summerbell et al.

Summerbell et al. is directed to weight reducing diets. The diets of the trial were directed to reducing weight in patents with a body mass index (BMI) greater than 27 (abstract). Three diets were administered. Diet 1 was a control. Diet 2 was a milk only diet. Diet three was a milk plus diet, which consisted of milk with the addition of unlimited amount of a single food (page 1488, interventions). It is disclosed that in the milk only diet patients achieved the highest overall mean weight loss (page 1489, first paragraph).

**Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to combine the teachings of Science Daily and Summerbell et al. and utilize calcium in a method of inducing weight loss in an individual suffering from obesity. One of ordinary skill in the art would have been motivated to utilize calcium in this type of method because Science Daily indicates that calcium decreases body fat. Therefore, it would have been obvious to utilize calcium in an individual who needs to loose body fat such as an obese person. Furthermore Summerbell et al. indicates that this type of administration has been shown to induce weight loss in obese patients.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding the administration of at least 57 servings of dairy per month (instant claims 1, 10, 12 and 19), the amount of calcium instant claimed and that of Science Daily is the same (at least 1000 mg/day). Therefore, depending on the source of the calcium it would have been obvious to one of ordinary skill in the art to determine the appropriate number of servings to consume in order to reach the required daily amount of at least 1000 mg/day.

Regarding instant claims 3-4, the Science Daily article meets the limitation of this claim because it is information packet that informs an individual that calcium-containing products can induce weight loss and that the daily calcium consumptions needs to be at least 1000 mg/day.

Regarding instant claims 5-6, Science Daily discloses that consumption of less than 780 mg of calcium a day does not result in weight loss. Therefore, there is a reasonable expectation that individuals before utilizing calcium to induce weight loss are consuming less than 780 mg/day of calcium.

Regarding instant claims 14 and 20-22, Science Daily discloses calcium in dosages as those instantly claimed. The source of the calcium in the Science Daily article is the same as those instantly claimed. Therefore, the mechanism of the calcium inducing weight loss would necessarily be the same.

Response to Arguments

While the rejection made in the Office action mailed on 12/28/07 was withdrawn, Applicant's arguments pertaining to Summerbell et al. will be discussed as that reference was maintained in the current rejection.

Applicant argues that Summerbell et al. does not disclose, teach or suggest that weight-related benefits are attributable to the calcium. Applicant argues that nowhere in Summerbell et al. it is disclosed that calcium directly induces weight loss.

Applicant's arguments filed February 14 2008 have been fully considered but are not deemed persuasive in view of the newly presented art. Science daily clearly indicates that it was known in the art at the time of the invention that calcium is directly responsible for the decreases in body fat seen in their two-year study (paragraph 1 and 4).

Applicant argues that they have previously submitted evidence showing the present invention's unexpected results. However the Applicant has not indicated where these results have been presented. The examiner can only find Applicant's arguments in terms of unexpected results relating to their finding that calcium inducing weight loss has caused to a shift in the scientific community and the food industry who Applicant claims support and endorse the methods of the present invention. However, the Science daily article predates the filing of Applicant's application. Therefore, it was known in the art prior to Applicant's invention that calcium causes weight loss.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner
Art Unit 1616